



Food and Drug Administration
Rockville MD 20857

NOV 30 1995

Re: CPI® Ventak® P2 AICD System
Docket No. 95E-0183

#20

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

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OFFICE OF THE SECRETARY

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. Re. 34,879, filed by Cardiac Pacemakers, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for CPI® Ventak® P2 AICD System, the medical device claimed by the patent.

The total length of the review period for CPI® Ventak® P2 AICD System is 1,178 days. Of this time, 620 days occurred during the testing phase and 558 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun:
December 20, 1991.

FDA has verified the applicant's claim that the date the Investigational Device Exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on December 20, 1991.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: August 30, 1993.

FDA has verified the applicant's claim that the Premarket Approval Application (PMA) for CPI® Ventak® P2 AICD System (PMA P930035) was initially submitted on August 30, 1993.

3. The date the application was approved: March 10, 1995.

FDA has verified the applicant's claim that PMA P930035 was approved on March 10, 1995.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Stuart L. Nightingale".

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Peter Forrest
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